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Biotechnology

Annual Report

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Report Highlights:

The Guatemalan Congress approved the Cartagena Protocol in September 2003, and the Protocol took effect in January 2005. The National Biosafety Framework law was drafted in August 2004 and since February 2005 has been held in the Health Commission of the Legislature, without resolution. This Framework goes beyond the Cartagena Protocol's strict mandate of regulating LMOs and includes within the same petition mechanism all food and feed products derived from GMOs. Neither academia nor the private sector supports the proposed Framework. The Biotechnology Commission has considered modifying the Framework to make it less restrictive. There are no major issues regarding health and GMO food consumption. The focus has been on the environment since Guatemala is a designated center for biological diversity. Commodity imports continue unimpeded.

Includes PSD Changes: No
Includes Trade Matrix: No
Annual Report
Guatemala [GT1]
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EXECUTIVE SUMMARY

The U.S. Census Bureau reports \$ 100 million of U.S. biotechnology products exported to Guatemala. Table 1 shows the main U.S. agricultural exports to Guatemala that may include deregulated biotech products.

Table 1
US Exports to Guatemala
CY 2005
Source: BICO

Commodity	Total Exports Value (In thousands of \$)
Coarse grains	67,949*
Soybeans	2,671*
Cotton	38,025
Soybean Meal	60,988*
Soybean Oil	15,736*
Other Vegetable Oils	2,489

The Guatemalan Congress approved the Cartagena Protocol in September 2003 by Legislative Decree 44-03, which was published in the official newspaper, the Diario de Centro América, Volume CCLXXII N. 72, on 10/13/03. The Protocol took effect in January 2005.

By the end of 2003, the Technical Office for Biodiversity (OTECBIO) executed the project GUA-02-G21 "Development of the National Biosafety Framework for Guatemala", financed by the United Nations Environmental Program (UNEP) and the Global Environment Facility (GEF) through the National Council of Protected Areas (CONAP). The project ended in August 2004 with the creation of the National Committee for Biosecurity Coordination (CNCB), composed of various government representatives for the preparation of the National Biosafety Framework. Participants in drafting this framework were government officials, NGOs, PVOs, and consumer and indigenous organizations. The Framework is an over-reaching law that seeks to regulate all aspects of biotechnology research and commercialization. The private sector and academia complained that they were not included in the drafting process and were only invited to the last meeting where the final document was presented. The initiative has a definite bias, greatly influenced by groups with extreme views.

The framework includes a regulatory, an administrative, and a decision-making system for risk assessment and management, and mechanisms for public participation and information. The Guatemala Biotech Framework complies with the "precautionary principle", giving authorities the power to deny any related activity (research, production, commercialization) independent of the scientific evidence. The Framework only considers a petition process for field trials. At the moment there are no specific laws concerning commercialization of GMOs. Modified seeds that have entered the country have been approved at research and field trial levels only. Cultivation of modified crops has not been approved yet; Ministry of Agriculture is waiting for a country's regulatory framework approval. Use of biotech products for food, feed, or processing has not been addressed. Guatemala has not gone on a reviewing process of regulated and/or deregulated GMO product list. At the moment, commodity imports have not been impeded at all.

BIOTECHNOLOGY TRADE AND PRODUCTION

Guatemala produces no biotechnology crops, but imports yellow corn and soybean products from the U.S. Guatemala is a recipient of USG food aid. The country relies on corn and soybean meal for the animal feed industry.

BIOTECHNOLOGY POLICY

Current Regulations

Guatemala does not have an official system for testing or monitoring LMOs. The national norm in effect is Agreement 393-98 and its amendment 476-98, by which the Ministry of Agriculture (MAGA) through its Unit for Norms and Regulations (UNR) requires a phyto genetic or zoo genetic certificate for the importation of GMOs for research and field-testing. The Agreement establishes general guidelines for the handling and transport of GMOs in order to prevent their dissemination outside of their approved uses. The Agreement also establishes rules for labeling and approval of research trials. This Agreement assigns responsibilities for those who perform tests and for commercial companies that develop or supply transgenic products.

When considering whether to approve the import of transgenic materials, the Agreement allows MAGA to require a technical report from a Biosafety Committee composed of the Institute of Agricultural Science and Technology (ICTA), the Ministry of Environment through the National Committee of Environment (MARN), the UNR, the National Council of Science and Technology (CONCYT) and the Agronomy School of the National University (Universidad de San Carlos de Guatemala). It also allows authorized staff from the MAGA Sanitary Area to inspect GMOs at the warehouses and experimental sites. At the moment, GMO evaluations have been restricted to modified soy and corn seed, exclusively at field trial level.

Guatemala's law includes the FAO International Treaty on Phyto Genetic Resources, intended to govern preservation and sustainable use of agricultural resources (Ministerial Agreement 177-95). The conventional law is applied in general to all food (there are no specifications for GMOs) and requires that the National Health Laboratory (LUCAM) analyze food to verify quality and safety. Imported processed food products should have a "sanitary registry" of reference, which should be processed in the Ministry of Health (MSPAS) Registry and Food Control Department. The requirements are general, "to show the product's original label (product name), and its qualitative composition". There are no laws in place to sample or test biotech products, and therefore, specific labeling is not required. All commodities are labeled to comply with nutritional information, only. For bulk commodities, no labeling is required.

At an environmental level, there is an article requiring foreign companies or institutions to ask for a permit at ICTA for germplasm collections. In 1989 a law on protected areas created CONAP, responsible for the conservation of biological diversity (Global Agreement on Biological Diversity, Legislative Decree 5-95, Published in the Official Newspaper, Volume CCLIII, N. 10, on 1/12/96). CONAP has the authority to decide restricted areas. A list of protected areas where GMOs are not allowed is available at <http://www.conap.online.fr/primera.htm>

Biotechnology Framework Proposal/Initiative

Guatemala drafted its biotechnology framework using as a reference norms from Mexico, Colombia, Panama, Nicaragua, Peru, Spain, Cuba, and Argentina. The Framework intends to rule “all activities related to research, experiments, submission, experimental and commercial release, production, commercialization, distribution, use, storage, import, export, transit and transport of GMOs”. The Framework includes the creation of the National Commission for Modern Biotechnology (CONASBIO), the Consultative Council and three technical-scientific committees to cover wildlife, food, agriculture and livestock.

CONASBIO’s main task is to provide orientation and advice for decision makers.

Representatives of MAGA, the Ministry of Economy (MINECO), MSPAS, MARN, universities, CONCYT, and two Consultative Council representatives make up CONASBIO. The Consultative Council functions as an assistance office to address opinions from different sectors of civil society. The technical-scientific committees are tasked with studying the risk evaluation document submitted by the applicant.

The Framework includes a general petition process to be followed when handling modified living organisms and their products. Deadlines are set in accordance to those established in the Cartagena Protocol. The proposed system for the authorization of GMOs is the following:

1. The person interested in importing GMOs should complete a request for a phyto genetic or zoo genetic certificate.
2. The request will be submitted to government officials from MAGA.
3. Government officials will review the request and attached documents. If the request is complete, it will be provisionally accepted and a technical file opened. If the request is not complete, it will be returned to the applicant.
4. Upon acceptance, the request will be filed with CONASBIO for technical assessment and recommendation. The Technical Scientific Committee will perform an analysis and risk study and the opinions from the Consultative Council will be considered at this time.
5. If approved, the government will require the applicant to publish a summary of the submitted application in the two largest national newspapers to inform the population and get opinions within a 20-day period from publication date.
6. CONASBIO will send the application to the Consultative Council who will then have 20 days to respond. CONASBIO will also send the file to the Scientific Technical Committees to analyze the request and the corresponding risk study, based on scientific procedures.
7. CONASBIO will notify the applicant of the final resolution within a period no longer than 270 calendar days.

The request for acquiring a phyto genetic or zoo genetic certificate, according to Title III, Article 31, establishes that “on the information required in case of GMOs and their products for human consumption and animal feed, the national authorities can require, at a minimum, the following information in relation to GMOs and their products intended as direct use for human food or animal feed, or for processing”:

1. Name and nature of the business.
2. Name and signatures of the authorities in charge.
3. Name and identity of the GMO.
4. Description of the gene modification, technique, resulting characteristics of the GMO.
5. Any exclusive identification of the GMO.

6. Taxonomic condition, common name, place of origin, characteristics of the receptor organism, or the parental organisms that may have relation with biotechnology security.
7. Origin centers and genetic diversity centers, if known, of the receptor organisms and/or parental organisms, and habitat description where the organisms may persist or proliferate.
8. The approved uses of the GMO.
9. Quantity or volume of the GMO.
10. A risk assessment report, attaching other countries' studies.
11. Suggested methods for the manipulation, storage, transport, safe use, including packaging, labeling, documentation, and elimination procedures under emergency situations, according to each situation.
12. Planned dates for the transnational movement.
13. Legal status of the GMO in the exporting country with detailed information on its prohibition in other countries if applicable.

The Framework also includes general guidelines for monitoring GMO related work under the supervision of MAGA. The Framework mandates that even if there is not enough scientific evidence to deny an import request, if the organism is deemed to potentially possess a risk for biodiversity or may have a negative social impact, the government officials can prohibit the import of the GMO (cited as the "precautionary principle"). The Framework also allows government officials to revoke a previously granted license if the GMO or derived product may possess a potentially negative impact. Additional information can be found at www.unep.ch/biosafety/development/devcountries/Gtctrypage.htm and <http://www.congreso.gob.gt/archivos/iniciativas/registro3105.pdf>.

Guatemala's biosafety framework focuses on the environment taking into consideration that Guatemala is a designated center for biodiversity. A study on biological diversity and potential risk by the introduction and manipulation of GMOs can be found at <http://www.unep.ch/biosafety/development/Countryreports/GTNBFPriorizacion%20.pdf>. CONAP recently published its "Third Report on National Achievements Within the Convention on Biological Diversity". Achievements include pursuing the implementation of the Cartagena Protocol.

The Biotechnology Framework does not consider coexistence between traditional agriculture (including organic) with biotechnology agriculture. Protected areas are considered biodiversity regions and no GMOs are allowed (Title IV Article 36). The Framework does not allow genetic manipulation of local flora and fauna without a license or permit (Title VIII, Article 58).

In practice, the Framework goes far beyond the Cartagena Protocol, including foods derived from LMOs in the same petition process required for LMOs.

CONAP is considering the proposals to amend the current version of the Framework. Changes may include considering GMO-derived food and feed products in a deregulated list. Modifications will be addressed towards a more flexible policy (petition protocol and time frame) where the country can comply as well with other international regulations and commitments.

Field Trials and Research

The private sector is concerned about the lack of opportunities to commercialize their biotech products under the Framework. These companies want to work with GMO lines because they understand their higher yield and productivity, reduced cost for chemical control, and direct

environmental benefit. The private sector has approached the Agriculture Minister to make known their disapproval of the Framework.

MAGA continues issuing permits for field-testing of biotechnology crops from transnational companies. Semillas, S.A., in cooperation with Monsanto, worked on a field trial with Yielgard gene in corn for Lepidopteron resistance. This company foresees testing other biotechnology with insect, herbicide, and water stress resistance. They have two projects approved by MAGA and are evaluating corn and soybean. Algodones Mayas S.A., also in cooperation with Monsanto, established a field trial with Liberty gene to develop glufosinate resistant cotton.

Two universities are working with GMOs. Universidad del Valle de Guatemala (UVG) has 2 laboratories where ring spot virus-resistant native papaya has been developed in collaboration with Cornell University. The Biology Department of Universidad de San Carlos de Guatemala has an Applied Entomology and Parasitology Laboratory (LENAP) that is producing taq polimerase, using a recombinant E. coli. Both UVG and LENAP are well equipped for DNA cloning, transformation, gene transference to other organisms, and field tests with GMOs.

Guatemala has two government institutions with the potential to work with modern biotechnology. ICTA has molecular markers and tissue culture laboratories. ICTA is responsible for authorizing studies and reference collections of crop species (Ministerial Agreement 177-98). ICTA is also in charge of approving field trials with GMOs (Ministerial Agreement 476-98). The Central America and Panama Nutrition Institute (INCAP) has microbiology and virology laboratories. INCAP has a program to evaluate the social impact of a GMO introduction into the country.

In total, including the above universities and government institutions, the country has 27 laboratories related to biotechnology, half of them working on agriculture and the other half with human health. These institutions are staffed by a total of 56 professionals, of which 9 have master degrees and 7 have PhDs. The working space of any of these laboratories is at most half the area of an average US laboratory. Most of the research is not at the molecular level but with basic biotechnology dealing with germplasm conservation and tissue culture propagation for sugar cane and vegetable production for local and export markets. Appendix 1 lists the Agricultural programs running in the country.

CAPACITY BUILDING AND OUTREACH

A scientist of Universidad del Valle de Guatemala (UVG) participated in USDA's Cochran Program in 2001 to receive training in transforming papaya for ring spot virus resistance. There is a great need to continue support and assistance for the evaluation and acceptance of GMO products exported from the United States. The majority of the Guatemalan population is illiterate; communities are easily manipulated according to the desires of special interest groups.

The most important strategy involves education of government policy makers, university professionals and opinion leaders about U.S. biotechnology policy, scientific risk assessment analysis, and international SPS (WTO) commitments, so that they can feel confidence in the safety of deregulated GMO products. Embassy Guatemala's Economic Section and FAS are working with GOG officials to educate key leaders. In 2005, Dr. Kitty Cardwell of USDA's Cooperative State Research, Extension, and Education Service held a 3-day seminar to analyze the U.S. science-based policy on biotechnology. FAS is including three key Guatemalans in the "Biosafety - An International Short Course in Environmental Aspects of Agricultural" under the Cochran Fellowship Program.

APPENDIX 1: BIOTECHNOLOGY-RELATED PROGRAMS RUNNING IN GUATEMALA

PROGRAM	PROJECT	FINANCIAL SOURCE
Molecular markers	Enhancement of Gemini virus resistant plants. Genetic resistance to diseases with economic impact in tomato.	FAUSAC – USAID FAUSAC - AGROCYT
Micro propagation	Banana, plantain, pony, izote, loroco, fir tree, potato, Persian lemon, sarsaparilla, blackberry, strawberry, orchid.	FAUSAC
Germplasm conservation	Yucca, sweet potato, sarsaparilla, sugar cane, chrysanthemum, African violet, Rabinal orange, Persian lemon	FAUSAC
Virus cleaning	Garlic, potato	ICTA - AGROCYT
Micro propagation	Fir tree Potato greenhouse acclimatizing	ICTA – FODECYT ICTA
Biotechnology	Sugar cane micro propagation Sugar cane varietal characterization using micro satellites	CENGICAÑA CENGICAÑA – ICTA
Vegetable protection	Virus resistance in papaya (RFLP, DNA cloning and transformation, gene transference, field trials) Citric species evaluation for determining presence of virus and viroids with economic relevance, cleaning and characterization previous to its propagation Determination of the causal agent for the “chocolate disease” in tomato (ELISA, PCR). Epidemiology surveillance for the coconut lethal yellowing; local measures for its control (monitoring). Coconut lethal yellowing study and search for native seed.	UVG - US Universities (including North Carolina) UVG – AGROCYT UVG – AGROCYT UVG – AGROCYT UVG – FACYT

	<p>Pest insect and disease evaluations, integrated pest management, and establishment of virus resistant Hawaiian papaya.</p> <p>Immunoimpression for detection of viral psorosis in citric production areas in Guatemala (ELISA).</p>	<p>UVG – IPM/CRSP</p> <p>UVG - FODECYT</p>
Biological control	<p>Metarrizum and parasitoid production for insect control</p> <p>Insect virus production</p> <p>Nematodes for virus control</p>	<p>Ingenio Pantaleon</p> <p>Ingenio La Union</p> <p>Ingenio Santa Ana</p>
Germplasm conservation and Micro propagation	<p>Sugar cane micro propagation</p> <p>Germplasm conservation and hybrid evaluation in coffee.</p> <p>Micro propagation of pineapple, cactus, papaya, pitaya, sweet potato, anthurius, vanilla, orchids, garlic, artichoke.</p> <p>Black berry micro propagation</p>	<p>CENGICAÑA</p> <p>ANACAFE – PROMECAFE, BIOFONTAGRO</p> <p>ICTA</p> <p>URL</p>
Molecular markers	<p>Corn germplasm characterization (SSR)</p> <p>Corn selection of lines with high protein quality (SCAR)</p> <p>Garlic germplasm characterization (AFLP)</p> <p>Black beans varietal characterization (AFLP)</p> <p>Black beans characterization of varieties and mutants (SSR)</p>	<p>ICTA – AGROCYT</p> <p>ICTA – FODECYT</p> <p>ICTA</p>

Source: "Current Status of Biotechnology in Guatemala". 2004. CONAP Technical Bulletin N. 17 (06-2004).